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10/502,417	02/15/2007	Bakulesh Mafatlal Khamar	21059/0206951-US0	2043

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EXAMINER	
GRASER, JENNIFER E	
ART UNIT	PAPER NUMBER
1645	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,417	KHAMAR, BAKULESH MAFATLAL	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-47 and 52-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-47 and 52-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 37 is objected to because of the following informalities: the phrase "related from the group consisting of" in line 3 should be changed to "selected from the group consisting of". Appropriate correction is required.

Claim Rejections - 35 USC § 112-Enablement

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-47 and 52-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention - The claims are drawn to methods of treating or managing cancer; improving the quality of life in a patient suffering from cancer; ameliorating symptoms associated with cancer comprising administration to a patient a pharmaceutical composition comprising an effective amount of heat killed *Mycobacterium w* **or** an enzymatic extraction of *Mycobacterium w* wherein the enzyme is selected from liticase and pronase.

The amount of direction/guidance/examples present -The instant specification in its present form, while reciting various preparations of

Mycobacterium w, does not specify which of the types was actually utilized nor how much of the composition was administered in the recited Examples. Therefore, there is insufficient information to enable the instant claims. The required information to support the instant claims, at a minimum, would be the actual composition administered to the patients (whole cells, disrupted cells, cell fractions, etc), the dosage administered, the route of administration, and the frequency of administration. The instant specification does recite 10 different preparations of Mycobacterium w pharmaceutical composition, i.e., heat killed whole cells, methanol extract, chloroform extract, sonicate, acetone extract, ethanol extract, and does not specify which of the types was actually utilized. Because of the wide variety of the composition preparations, the actual constituents in each of the pharmaceutical compositions also vary greatly. Thus, without knowing exactly which preparation was utilized, there is insufficient information to enable the instant claims which merely recite "a pharmaceutical composition comprising an effective amount of" either "Mycobacterium w" or "a" constituent of Mycobacterium w. Additionally, there are no method steps for the various solvent extractions recited. The components of the extract would be expected to vary based on the method steps used. Accordingly, it is unclear which actual extract possesses any of the therapeutic properties and it would take one of skill in the art undue experimentation to practice the invention as claimed.

Cancer treatment is an extremely unpredictable art with a solid statistical data required to support it. The instant specification shows only anecdotal

evidence of a few isolated patients with various symptoms and does not recite the actual composition used or the amount. These isolated, independent anecdotal examples are not sufficient to enable the claimed methods. The anecdotal case studies contain so many different variables and factors it is unclear what is actually causing the different effects and if they can be attributed to the Mycobacterium w composition. None of the isolated incidents are sufficient to support claims broadly drawn to method for treatment or management of any cancer, nor do they support a method for the amelioration of symptoms associated with any cancer or improvement in quality of life in a cancer patient.

Additionally, the term "cancer" is very broad. There are numerous types of cancers and stages of cancers, e.g., leukemia, ovarian cancer, bone cancer, breast cancer, pancreatic cancer, lymphoma, cervical cancer, prostate cancer, lung cancer, brain cancer, colon cancer, testicular cancer, bladder cancer, breast cancer, kidney cancer, oral cancers, skin cancers, gall bladder cancer, liver cancer, rectal cancer, retinoblastoma, etc.; however the specification is not enabled for the scope of treatment/management/amelioration of symptoms of this broad class of cancers.

Response to Applicants' Arguments:

Applicants have stated on page 6 of their response that the actual composition used in the specification examples demonstrating medical effect (as in Examples 4 to 9) was the one provided in Example 1a which consists of 0.5 X

10^9 heat killed whole cells of *Mycobacterium w* in 0.1 ml. The route of administration was intradermal. They state that "the other disclosed compositions are usable". This has been fully and carefully considered, but is not deemed persuasive in overcoming the rejections as it is not commensurate in scope with the claimed invention which allows for the use of enzymatic extracts of *Mycobacterium w* and any mode of administration.

The 1.132 Declaration of inventor Dr. Kahmar and the specification seem to support the treatment of muscle invasive bladder cancer with the use of intradermal administration of heat killed whole cells of *Mycobacterium w* in conjunction with radiotherapy. However, the claims are not limited to this scope of invention. With respect to the other cancers and declaration at section 13, no results are provided. It is stated that studies are on-going (see (a)-(d)) . It is noted that the Mycobactierum w is used in conjunction with other agents. Information as to the composition used is also not provided. The specification fails to teach alleviation of the specific symptoms recited in instant claim 69, e.g., *no* results are provided which support the amelioration of pain, cough, abnormal hemoglobin, breathlessness, dysphagia, neutropenia or irregular sleep. Further, there are no working examples of reduced side effects of thrmobcytopenia, anemia, nausea, vomiting or mucositis. 'A method of providing palliative care for cancer comprising administering an effective amount of a pharmaceutical compositions comprising intradermal administration of heat killed whole cells of *Mycobacterium w* ' and 'methods of treating bladder cancer comprising intradermally administering an effective amount of a pharmaceutical composition

comprising heat killed whole cells of *Mycobacterium w*' in conjunction with radiotherapy' appear to be more in line with what has been demonstrated. The mention of protocol for clinical trials which are upcoming or on-going does not provide sufficient support for what was taught in the specification at the time the application was filed. There are no results provided which demonstrate the effectiveness of the methods instantly claimed.

The instant specification shows only evidence of a very few isolated patients with various symptoms and does not recite the actual composition in the methods. A direct correlation to the product administered and the symptoms achieved has not been shown, nor has a statistical portion of treated subjects been shown.

The dosage amounts, product to be used, route and frequency of administration are not merely 'routine experimentation. Rather, it is akin to invention. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail

must be provided in order to enable members of the public to understand and carry out the invention." As stated in the rejection set forth above, the instant specification shows only anecdotal evidence of a few isolated patients with various symptoms and does not recite the actual composition used or the amount. These isolated, independent anecdotal examples are not sufficient to enable the claimed methods. The anecdotal case studies contain so many different variables and factors it is unclear what is actually causing the different effects and if they can be attributed to the Mycobacterium w composition. None of the isolated incidents are sufficient to support claims broadly drawn to method for treatment of any cancer, nor do they support a method for the amelioration of symptoms associated with any cancer or improvement in quality of life in a cancer patient. While supporting data can demonstrate effectiveness, it cannot be used to provide essential elements missing from the application's specification at the time of filing.

Status of Claims:

No claims are allowed. The prior art has taught the *idea* of the use of Mycobacterium w in pharmaceutical compositions for treating leprosy and treating HIV; however, the prior art does not teach or suggest using a pharmaceutical composition of Mycobacterium w to treat cancer, improve the quality of life in a patient with cancer or a method of ameliorating symptoms associated with cancer.

3. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

10/15/10